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510(k) SUMMARY

IBC CMO2 Flow Through Cuvette

The IBC CMO2 Flow Through Cuvette is a single piece, single use, disposable component intended for use with the Bentley OxySat Monitor as a direct substitute for the Bentley OTC Flow Through Cuvette. It is sold sterile and pyrogen free in a Tyvek peel pouch. It is substantially equivalent to the Bentley OTC Flow Through Cuvette which is marketed by the Bentley Division of Baxter Healthcare.

TABLE OF COMPARISON

CHARACTERISTIC	CMO2 CUVETTE	OTC CUVETTE
Packaging	Single, sterile and disposable	Single, sterile and disposable
Construction	Single piece molded	4 molded pieces assembled
Sizes	1/4", 3/8", 1/2"	1/4", 3/8", 1/2"
Material	Polycarbonate	Polycarbonate
Sterilization	Ethylene Oxide	Ethylene Oxide
Accuracy	Identical (r=.998)	Identical (r=.998)
Toxicity	Tripartite Guidelines	Tripartite Guidelines
Blood Compatibility	Non-Hemolytic	Non-Hemolytic

DISCUSSION OF SIMILARITIES AND DIFFERENCES

The IBC CMO2 Flow Through Cuvette is constructed of a single piece of injection molded polycarbonate while the Bentley OTC Flow Through Cuvette is Assembled by adhesively bonding 4 molded pieces together. The reason for the single piece construction in the CMO2 is to reduce cost of manufacture while at the same time eliminating a source of leaks and product failure (the bonds) and finally to control the final geometry for the least variation in the attachment fit with the OxySat Transducer. The functional geometry and material of construction are identical as is the performance when used according to manufacturer's instructions in the Bentley OxySat monitoring system.